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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,508	09/12/2005	Jonathan Alexander Terrett	2543-1-038PCT/US	2562

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EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,508	TERRETT, JONATHAN ALEXANDER	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed October 31, 2007 in response to the Office Action of June 27, 2007 is acknowledged and has been entered. Previously pending claims 1-10 and 12-27 have been cancelled and claim 11 has been amended.

2. Claims 11 and 28-30 are pending and under consideration.

3. The following rejections are being maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4 Claim 11 remains rejected and new claims 28-30 are rejected under 35 USC 112, first paragraph for the reasons previously set forth on pages 3-7, section 8 of the Office Action of June 27, 2007.

Applicant argues that Claim 11 is amended to be directed to a method for the treatment of breast, lung and/or pancreatic cancer in a subject, which comprises administering to said subject a therapeutically effective amount of an antibody which is a monoclonal, chimeric, humanised or completely human antibody, wherein said antibody specifically binds to a NKCC1 polypeptide which consists of the amino acid sequence of SEQ ID NO: 1. Applicant argues that a skilled practitioner would view the data presented in the specification as evidencing that the presently claimed method is practicable and, moreover, that the claimed method has a reasonable chance of success. More particularly, a skilled practitioner would understand that an antibody specific for NKCC 1 would target NKCC 1 present on breast, lung and/or pancreatic cancerous cells and

would be able, based on the teachings of the specification, to make and test such an antibody without undue experimentation.

Applicant's arguments have been considered but have not been found persuasive because, as previously set forth, the development of novel cancer therapeutics is unpredictable. Applicant has not provided any empirical evidenced in the specification or the art of record that an antibody directed to NKCC1/SEQ ID NO: 1 would treat breast, lung, or pancreatic cancer in any model system. Thus, in the absence of such evidence, one of skill in the art could not predictably use the method as claimed without undue experimentation.

Applicant argues that the present invention represents the first disclosure of NKCC1 protein over-expression in breast, lung and/or pancreatic cancers. This discovery led to the realization of a new and credible utility of using an antibody directed against NKCC 1, a previously unidentified protein target in these cancers, as a therapeutic. In view of the above, Applicant asserts that the claim to a method for the treatment of breast, lung and/or pancreatic cancer is commensurate with the present inventor's contribution to the art, i.e., the provision of a new target for breast, lung and/or pancreatic cancer treatment using an antibody specific for that target. This assertion is supported by mRNA over-expression data presented in Example 2, immunohistochemistry data presented in Example 3, and immunocytochemistry data presented in Example 4 of the specification. Applicant argues that that on the basis of the data presented in the specification, a skilled practitioner would understand and readily believe and accept that an antibody specific for NKCC 1, and in particular, a monoclonal, chimeric, humanised or completely human antibody would target NKCC1 protein present on cancerous cells since NKCC1 expression is increased in such cells. The making and testing of antibodies for the

claimed use, while requiring some experimentation by a skilled artisan, does not require undue experimentation. A skilled artisan can readily make and test anti-NKCC 1 antibodies using the teachings of the specification and his/her own knowledge and skills. In particular, the specification teaches: (i) techniques for the production of antibodies that bind to an antigen immunospecifically (in paragraphs [0116] to [0124]); (ii) methods for selecting agents (including antibodies) for therapeutic use (in paragraphs [0163] to [0174]; and (iii) antibody-drug conjugation techniques (in paragraph [0160].

Applicant's arguments have been considered but have not been found persuasive because although NKCC1/SEQ ID NO: 1 is expressed in breast, lung, and pancreatic cancer and a skilled artisan could make and test antibodies to NKCC1/SEQ ID NO: 1 for therapeutic activity, the requirements of 35 USC 112 are not drawn to making and testing the inventions, but rather the specification must contain the manner and process of making and using the invention.
In particular, screening assays do not enable the claimed invention because the court found in (*Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004) that screening assays are not sufficient to enable an invention because they are merely a wish or plan for obtaining the claimed chemical invention.

Applicant's arguments have been considered, but have not been found persuasive and the rejection is maintained.

Information Disclosure Statement

5. Applicant argues that the Examiner has indicated that a compact disc (CD) can not be used to submit an Information Disclosure Statement (IDS) listing or copies of documents cited in an IDS. The two references Applicant attempted to submit via CD are exceedingly large

documents, indeed the WO 01/22920A2 patent application is 9,787 pages long. The intent of Applicant's submission of these references on a CD was, therefore, to expedite delivery and entry of these documents into the record.

Applicant arguments have been considered, but have not been found persuasive because, unfortunately, although the documents are large MPEP 609.04(a) II (D) states that a CD cannot be used to submit an IDS listing or copies of the documents cited in the IDS, thus the contents of a submitted CD are not scanned or placed into the file for review during the processing of the Application.

6. All other objections and rejections recited in the Office Action of June 27, 2007 are withdrawn.

7. No claims allowed.

8. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application

which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal form, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Ungar

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Peter J. Reddig
Examiner
Art Unit 1642

PJR